HFI-35

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DEPARTMENT OF HEALTH & HUMAN SERVICES M793N Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

April 3, 1997

WARNING LETTER
CIN-WL-97-293

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert L. Vail, President
Vail Products, Inc.
235 First Street
Toledo, Ohio 43605

Dear Mr. Vail:

The Food and Drug Administration (FDA) conducted an inspection on March 17 & 18, 1997 of your firm that manufactures enclosed canopy style patient beds. These are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code Of Federal Regulations (CFR), Part 820.

The following deviations from Device GMP's were documented;

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures.

- Failure to establish a formally designated unit to review, establish, and maintain written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness or performance of the beds and determine whether or not an investigation is necessary.

- Failure to establish and implement a failure investigation program to determine whether the beds or any of their components fail to meet performance specifications. For example: there were about 15 product questionnaires on which the owner-user complained that side rails bend too easily, didn't function properly, stick when raised or lowered, and that the black insert on the rails wasn't functional or came off. There were no failure investigations for any of these issues.

- Failure to have written procedures for device change control to assure the design change is adequate. For example: the Vail 1000 and Vail 2000 side rail design was changed with no formal procedure.

- Failure to have a written MDR procedure to identify, evaluate, document and process medical device reportable events.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

LEB/clc